

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 13 AUG 2008	
Applicant's or agent's file reference 2755.002WO2	FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US07/65789	International filing date (day/month/year) 02 April 2007 (02.04.2007)
Priority date (day/month/year) 31 March 2006 (31.03.2006)	
International Patent Classification (IPC) or both national classification and IPC IPC: A61F 2/02(2006.01) USPC: 424/427	
Applicant FORSIGHT LABS, LLC	

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 16 July 2008 (16.07.2008)	Authorized officer Sharon E. Kennedy Telephone No. 571-272-1600
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Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE
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International application No.

PCT/US07/65789

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in electronic form.
☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

**WRITTEN OPINION OF THE
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International application No.
PCT/US07/65789

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>4-6, 15, 16, 34, 38-42</u>	YES
	Claims <u>1-3, 7-14, 17-33, 35-37, 43-47</u>	NO
Inventive step (IS)	Claims <u>15, 16, 34, 40</u>	YES
	Claims <u>1-14, 17-33, 35-39, 41-47</u>	NO
Industrial applicability (IA)	Claims <u>1-47</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-3, 7-14, 17-33, 35-37, 43-45 lack novelty under PCT Article 33(2) as being anticipated by Prescott, US 2006/0020248 A1. Body 12 made of a soft impermeable material, preferably silicon, which anticipates applicant's claimed "sheath" in the lack of further defining features. Note also figure 11 which discloses a more sheath-like configuration. Porous head 24 is made of a second material, preferably silicon, which permits drug diffusion from body 12. Claims 9 and 25-27, 32, 33, 35-37, 45 are included because logically, head 24 is compressible since it is a soft silicon, and it may be manipulated by compressing the retention flange to a smaller profile, which is the likely method of insertion given the state of the art at that time. Regarding claim 44, the feature is considered inherent in view that the body 12 comprises a soft resilient material.

Claims 4-6, 39, 41, 42 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph above and further in view of Freeman, US 5,283,063. These claims are directed to a hydrogel swellable retention means, which is shown by Freeman. It would be obvious to one of ordinary skill in the art to apply a swellable retention means as shown by Freeman to the Prescott device so that the Prescott device could be more firmly and gently retained.

Claims 45-47 lack novelty under PCT Article 33(2) as being anticipated by Freeman, US 5,283,063. Freeman discloses an expanding hydrogel core which swells and expands the retaining member 30. See column 6, lines 52-63. Coatings are disclosed in column 7, lines 31-52. Freeman does not disclose a drug.

Claims 15, 16, 34 and 40 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the particular retention structure comprising the tubular body with arms and slots, in combination with the other recited features, or the wings connected to the sheath as described in claim 40, in combination with the other recited features. Regarding claim 34, the prior art does not show or suggest a punctum plug which may be reloaded by removing the drug core from the retention structure while the retention structure remains anchored to the lumen.

Claims 1-47 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.